K132570

APR 2 9 2014

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510(K) SUMMARY
Electric Handpiece System

1. Date Summary Prepared: March 25,2014

2. Submitter Information

   510(k) Owner: TTBIO CORP.

   2F, No.7, 6th Road, Industry Park, Taichung, Taiwan, R.O.C. 40755

   Contact Person: Jo S.C. Lee/QA Engineer

   Phone: 886-4-23595958/e-mail: jo@ttbio.com

3. Device Name

   Trade Name: Thor 700 Electric Handpiece System

   Common Name: Dental Handpiece and Accessories

   Classification Name: Dental Handpiece and Accessories

   (21 CFR 872.4200, Product Code EBW)

4. Predicate Device: Siro Torque L, (K031584)

5. Device Description:

   Thor 700 Electric Handpiece System is composed of a system unit, which is connected to a power supply and a control tube, that system unit drives a dental drive device. The system unit converts pneumatic output from the dental treatment unit to control the torque, speed and directional rotation of the dental drive device. The dental drive device, in turn, provides the control for motorized dental handpieces. The inputs to the system unit are supplied by a dental treatment unit. Inputs can also be controlled by the foot pedal of the treatment unit.

6. Intended Use:

   Thor 700 Electric Hnadpiece system is intended to convert pneumatic output from a dental treatment center to electrical energy for operation of electrically-driven dental handpiece.

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7. Substantial Equivalency:

Substantial Equivalence Table		
Descriptive Information	**Device (Thor 700)**	**Predicate devices (SiroTorque L; K031584)**
Intended for Use	Thor 700 is intended to convert pneumatic output from a dental treatment center to electrical energy for operation of electrically-driven dental handpieces.	The Siro Torque L is intended to convert pneumatic output from a dental treatment center to electrical energy for operation of electrically-driven dental handpieces.
Components	System unit, power supply, control tube and a dental drive device (micromotor).	Control unit, power supply, hose and two alternative electric micromotors.
Principle of operation	External power was supplied to Thor 700 through a power supply. Cooling water and cooling air are supplied by the dental treatment center and the foot padel controls the dental drive device speed.	External power was supplied to SiroTorque L through a power supply. Cooling water and cooling air are supplied by the dental treatment center and the foot padel controls the micromotor speed.
Composition of Materials	Aluminum, Stainless Steel, Plastic	Aluminum, Stainless Steel, Plastic
The patient-contacting portions of the device	No contact with patients	No contact with patients
System unit		
Speed Control	Yes	Yes
Digital speed readout	Yes	Yes
Installation capability	external	internal/external
Individually programmable settings	2	2
Forward/reverse switches	Yes	Yes
Spray water pressure	36 psi (2.5bar)	29 psi (2.0 bar)
Spray air pressure	29 psi (2.0bar)	39 psi (2.7 bar)
Power supply		
Voltage input	AC : 100 – 240 V AC 50/60 Hz	AC : 100 – 240 V AC 50/60 Hz
Voltage output	DC : 48V DC	DC : 24V DC
Dental drive device		
Motor speed	2000 ~ 40000 rpm	2000 ~ 40000 rpm
Motor diameter	22 mm	21 mm
torque	3 N-cm maximum	2.4 N-cm maximum
weight	62 grams	100 grams

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Substantial Equivalence Table		
Descriptive Information	**Device (Thor 700)**	**Predicate devices (SiroTorque L; K031584)**
Technical Specification		
Cooling air pressure	30 NL/min	30 NL/min
Spray air pressure	36 psi (2.5bar)	39 psi (2.7bar)
Spray water pressure	29 psi (2.0bar)	29 psi (2.0bar)
Torque	max. 3.0 N-cm	max. 2,4 N-cm
Speed range	2000~40000 rpm	2000~40000 rpm
Coupling dimensions	According to ISO-3964	According to ISO-3964
Hose connections	According to ISO-9168	According to ISO-9168
Noise	According to ISO-11498	According to ISO-11498

Thor 700 Electric Handpiece System is substantially equivalence to the Siro Torque L (K031584) on equivalence intended uses and technical characteristics.

8. Discussion of non-clinical data:

   Testing of electromagnetic compatibility and electrical safety has been conducted in accordance with IEC 60601-1-2 and IEC 60601-1. The software has been successfully validated to confirm the performance of Thor 700 Electric handpiece System according to the FDA guidance-" General principle of Software Validation; Final Guidance for Industry and FDA staff", dated January 11, 2002.

   The performance testing was conducted according to ISO 11498 and sterilization validation 132°C for 15 minutes, drying time for 30 minutes was performed in accordance to ANSI/AAMI ST79:2010.

   Biocompatibility testing was conducted according to ISO 10993-10 and the results showed that No erythema and no oedema were observed on the skin of the rabbits. The response of the test article was categorized as "negligible".

9. Discussion of Clinical Tests Performed:

   N/A

10. Conclusion:

    The above descriptions coincide with the substantial equivalence, Siro Torque L (K031584). They are substantial equivalent to the predicate device in terms of its intended use, operating principles and functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 29, 2014

TTBIO CORPORATION
Shu-Ching Lee
Engineer
2F, No.7, 6th Road Industry Park
Taichung, Taiwan R.O.C 40755

Re: K132570
Trade/Device Name: Electric Handpiece System, Model Thor 700
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EBW
Dated: March 25, 2014
Received: March 27, 2014

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Acting Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(K) Number (If Known): K132570

Device Name: Electric Handpiece System, Model Thor 700.

Indications for Use:

Thor 700 Electric Handpiece System is intended to convert pneumatic output from a dental treatment center to electrical energy for operation of electrically-driven dental handpiece.

CAUTION: Federal (US)) law restricts the use of this device to licensed professionals

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

Sheena A. Green -S
2014.04.28 12:30:43 -04'00'